



**UNITED STATES DEPARTMENT OF COMMERCE**  
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/419,545	10/18/99	DARJI	29473/10277

HM12/0309  
MARSHALL O'TOOLE GERSTEIN MURRAY  
AND BORUN  
6300 SEARS TOWER  
233 SOUTH WACKER DRIVE  
CHICAGO IL 60606-6402

EXAMINER

DEVI, S

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 03/09/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/419,545

Applicant(s)

Darji et al.

Examiner

S. Devi, Ph.D.

Group Art Unit

1645



☒ Responsive to communication(s) filed on 01/24/01.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire one month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-16 ~~is~~ are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☐ Claim(s) \_\_\_\_\_ is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 1-16 are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

**Restriction/Election**

- 1) Claims 1-16 are under prosecution.
- 2) **Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.
- 3) Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-10, drawn to an attenuated *Salmonella* strain and a vaccine comprising the same, classified in class 424, subclass 93.48.
  - II. Claims 11 and 12, drawn to a method for expression-screening of heterologous genomic DNA libraries using the attenuated *Salmonella* strain, classified in class 935, subclass 80.
  - III. Claims 13 and 14, drawn to a method of producing an attenuated *Salmonella* strain, classified in class 435, subclass 91.4.
  - IV. Claim 15, drawn to a method of producing a protein as an expression product of an attenuated *Salmonella* strain, classified in class 435, subclass 69.1.
  - V. Claim 16, drawn to a method of producing an immune response to an attenuated *Salmonella* strain by administration of the strain, classified in class 424, subclass 258.1.
- 4) Inventions I through V are distinct from each other. Invention I is directed to an attenuate bacterial strain. Inventions II through V are directed to distinct methods which differ from one another in method steps, parameters, reagents or compositions used, and ultimate goals accomplished.
- 5) Inventions I and II, inventions I and IV and inventions I and V are related as product and

processes of using the product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the processes of using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different processes of using that product (M.P.E.P 806.05(h)). In the instant case, the attenuated *Salmonella* strain can be used as a source of coating antigen in an *in vitro* diagnostic assay. The method of producing a protein of invention IV can be practiced without using the strain of invention I, for example, by chemically synthesizing the protein.

6) Inventions III and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP 806.05(f)). In the instant case, the attenuated product of invention I can be made by a process materially different from the process of invention III by chemical mutation or serial passage.

Because these inventions are distinct for the reasons given and have acquired a separate status in the art as shown by their different classification/subclassification and divergent subject matter, restriction for examination purposes as indicated is proper.

7) Applicants are advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R 1.143).

8) Applicants are reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filled petition under C.F.R 1.48(b) and by the fee required under 37 C.F.R 1.17(h).

9) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A voice mail message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on Examiner's voice mail system.

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If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SD

S. Devi, Ph.D.  
Patent Examiner  
March 2001